PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 6395-66078-02	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/US2004/032378	International filing date *(day/month/year)* 01.10.2004	Priority date *(day/month/year)* 17.10.2003
International Patent Classification (IPC) or national classification and IPC G01N1/24, G01N15/00		
Applicant THE GOVERNMENT OF THE UNITED STATES OF AMERICA..et		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17.08.2005	26.01.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Timonen, T Telephone No. +49 89 2399-5666

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US2004/032378

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-23	as originally filed

Claims, Numbers

1-6, 15-27	as originally filed
7-14, 28-38	received on 09.01.2006 with letter of 05.01.2006

Drawings, Sheets

1/10-10/10	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1,2,4,8-9,22,27-29
Inventive step (IS)	Yes:	Claims	12-21,34-38
	No:	Claims	3,5-7,10-11,23-26,30-33
Industrial applicability (IA)	Yes:	Claims	1-38
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

1. Reference is made to the following documents:

   D1: US-A-4 941 899 (LIU ET AL) 17 July 1990 (1990-07-17)

Objections pursuant to Article 33(2) PCT (Novelty)

2. Document D1 discloses an apparatus for collecting airborne particles comprising
   - a collection vessel (23) with an open end and a closed end,
   - a collection vessel retaining member (17,25) adapted to be removably coupled to the collection vessel,
   - an air-inlet conduit (15) in the retaining member for permitting air to flow into the collection vessel through the open end,
   - an air-outlet conduit (19) for permitting air to exit the collection vessel; wherein
   - the inlet and outlet conduits are configured in such a way that the air flowing into collection vessel coupled to the retaining member establishes a cyclonic flow path separating the airborne particles from the air.

   See Figure 1 and column 2, lines 21-51.

   Accordingly, the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

   It should be noted that, although it has no been explicitly disclosed in D1 that the cyclonic flow path extends into the collection vessel (23), it is implicitly clear that the cyclonic flow path starting in the retaining member (17) does not suddenly stop at the point where the collection vessel (23), having the same measurements as the retaining member (17), starts but rather extends in to the collection vessel, see Figure 1.

2.1 The air-inlet conduit (15) according to D1 is non-orthogonal to the plane that is parallel to the open and of the collection vessel (23), see Figure 1. Accordingly, the subject-matter of claim 2 is not new in the sense of Article 33(2) PCT.

2.2 The air-outlet conduit (19) according to D1 extends generally axially relative to the

collection vessel (23), see Figure 1. Accordingly, the subject-matter of claim 4 is not new in the sense of Article 33(2) PCT.

2.3 According to D1, the collection vessel (23) is a first collection vessel, the air-inlet conduit (15) is a first air-inlet, the air-outlet conduit (19) is a first air-outlet; and

- the retaining member (17,25) is adapted to be removably coupled to a second collection vessel (30),
- the retaining member (17,25) comprises a second air-inlet (26) and a second air-outlet (38), the first air-outlet (19) being connected to the second air-inlet (26), in such a way that
- the air flowing from the first air-outlet (19) flows into the second collection vessel (30) through the second air-inlet (26); wherein
- the second air-inlet and air-outlet are configured in such a way that a cyclonic flow separating the airborne particles from the air is established.

See Figure 3, and column 2, line 52 - column 3, line 51.

Accordingly, the subject-matter of claim 8 is not new in the sense of Article 33(2) PCT.

2.4 According to D1, the particles deposited in the first collection vessel (23) are generally larger than the particles deposited in the second collection vessel (30), see column 2, lines 49-51. Accordingly, the subject-matter of claim 9 is not new in the sense of Article 33(2) PCT.

3. Claim 22 defines a method analogue to the apparatus of claim 1. Therefore, the objections under item 2 above apply *mutatis mutandis* to the subject-matter of claim 22 which, accordingly, is not new in the sense of Article 33(2).

3.1 Claim 27 defines a method analogue to the apparatus of claim 8. Therefore, the objections under item 2.3 above apply *mutatis mutandis* to the subject-matter of claim 27 which, accordingly, is not new in the sense of Article 33(2).

3.2 Claim 28 defines a method analogue to the apparatus of claim 9. Therefore, the objections under item 2.4 above apply *mutatis mutandis* to the subject-matter of claim

28 which, accordingly, is not new in the sense of Article 33(2).

3.3 According to D1, analysis is performed on the particles collected in the collection vessel. Accordingly, the subject-matter of claim 29 is not new in the sense of Article 33(2) PCT.

Objections pursuant to Article 33(3) PCT (Inventive Step)

4. Dependent claims 3, 5-7, 10-11 and 23-26, 30-33 would appear to define minor modifications to the apparatus or method respectively. These modifications are either well known in the art or merely workshop modifications. Hence, the person skilled in the art would carry them out in accordance with the circumstances without having to exercise any inventive skill whatsoever. Accordingly, the subject-matter of the above-mentioned claims does not contain an inventive step in the sense of Article 33(3) PCT.

Further observations considering Article 33(2) and 33(3) PCT

5. The subject-matter of claim 12 differs from that disclosed in the closest prior art D1 (see above) in that the collection vessel comprises a microcentrifuge tube having an open end that is orthogonal to a line extending longitudinally with respect to the tube and in that the air-inlet conduit is non-orthogonal and non-parallel to the plane of the open end of the tube.

Accordingly, the subject-matter of claim 12 is new in the sense of Article 33(2) PCT.

The technical problem addressed by the above mentioned difference is to make the collecting apparatus compatible with commonly used laboratory analyzers.

The above mentioned technical problem has not been recognised in the available prior art, nor have the technical features required to solve it been disclosed or hinted at. Accordingly, the subject-matter of claim 12 would appear to contain an inventive step in the sense of Article 33(3) PCT.

Furthermore, the subject-matter of claim 34, defining a method analog to the

apparatus of claim 12, would appear to fulfill the requirements of Article 33(2) and 33(3) PCT with respect to novelty and inventive step.

Further observations on the form and content of the international application

6. In addition to the objections above, the following should be noted.

6.1 Independent apparatus claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

6.2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor are these documents identified therein.

6.3 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

6.4 The vague and imprecise statement in the description on page 23 implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them.

6.5 Claims 32 and 33 seek to define the method by features of the collected particles. As these particles are not a part of the method, the method should not have been defined by their features. Accordingly, the subject-matter of claims 32 and 33 does not fulfill the requirements of Article 6 PCT with respect to clarity.

7. The apparatus of claim 6, wherein the first passageway extends generally tangentially with respect to an inner surface of the collection vessel.

8. The apparatus of claim 1, wherein:

the collection vessel is a first collection vessel, the air-inlet conduit comprises a first air-inlet conduit, and the air-outlet conduit comprises a first air-outlet conduit; and

the retaining member is adapted to be removably coupled to a second collection vessel, the retaining member further comprising a second air-inlet conduit and a second air-outlet conduit, the first air-outlet conduit being in fluid communication with the second air-inlet conduit so that air flowing through the first air-outlet conduit flows into the second collection vessel through the second air-inlet conduit and exits the second collection vessel through the second air-outlet conduit, the second air-inlet conduit and second air-outlet conduit being configured to establish a cyclonic flow path in the second collection vessel to cause airborne particles to separate from the air flowing through the second collection vessel.

9. The apparatus of claim 8, wherein the particles deposited in the first collection vessel are generally larger than the particles deposited in the second collection vessel.

10. The apparatus of claim 8, wherein the retaining member is configured to support the first and second collection vessels in the same orientation.

11. The apparatus of claim 10, wherein the retaining member is configured to support the first and second collection vessels in a generally vertically upright orientation.

12. An apparatus for use in collecting airborne particles comprising:

a collection vessel in which airborne particles are collected for analysis, the collection vessel comprising a microcentrifuge tube having an open end that is orthogonal to a line extending longitudinally with respect to the tube;

an air-inlet conduit for conducting air into the collection vessel, the air-inlet conduit extending at an angle with respect to a plane that is parallel to the open end, the air-inlet conduit being non-orthogonal and non-parallel to said plane; and

an air-outlet conduit for conducting air out of the collection vessel;

wherein the air-inlet conduit and the air-outlet conduit are situated to cause air flowing through the collection vessel to create a vortex, thereby causing airborne particles to separate from the air flowing through the collection vessel.

13. The apparatus of claim 12 wherein:

the collection vessel is a first collection vessel, the air-inlet conduit comprises a first air-inlet conduit, and the air-outlet conduit comprises a first air-outlet conduit; and

the apparatus further comprises:

a second collection vessel;

a second air-inlet conduit in fluid communication with the first air-outlet conduit so that air flowing through the first air-outlet conduit is conducted into the second collection vessel through the second air-inlet conduit, the second air-inlet conduit being non-orthogonal to a line extending longitudinally with respect to the second collection vessel; and

a second air-outlet conduit for conducting air out of the second collection vessel;

wherein the second air-inlet conduit and the second air-outlet conduit are situated to cause air flowing through the second collection vessel to create a vortex, thereby causing airborne particles to separate from the air flowing through the second collection vessel.

14. The apparatus of claim 13, wherein the first collection vessel is supported in the same orientation as the second collection vessel.

28. The method of claim 27, wherein the particles collected in the second collection vessel are generally smaller than the particles collected in the first collection vessel.

29. The method of claim 27, further comprising performing an analysis on the particles that are collected in the second collection vessel.

30. The method of claim 27, wherein the analysis is performed while the particles are still in the second collection vessel.

31. The method of claim 22, wherein the analysis of the particles is performed while air is flowing through the collection vessel.

32. The method of claim 22, wherein the particles are bioaerosols.

33. The method of claim 22, wherein the particles collected in the collection vessel are approximately equal to and greater than 2 microns in size.

34. A method for collecting airborne particles for analysis, the method comprising:

flowing air through the open end of a microcentrifuge tube along a flow path in a direction that extends generally tangentially with respect to an inner surface of the microcentrifuge tube, the open end being orthogonal to a line extending longitudinally with respect to the tube, the flow path being non-orthogonal and non-parallel to a plane defined by the open end, wherein the air flowing through the microcentrifuge tube establishes a cyclone; and

separating airborne particles from the air flowing through the microcentrifuge tube.

35. The method of claim 34, wherein the air flowing through the microcentrifuge tube establishes a reverse-flow cyclone.

36. The method of claim 34, wherein the air flowing into the microcentrifuge tube is conducted through an inlet conduit of an air-flow fitting coupled to the microcentrifuge tube, and wherein air flowing out of the microcentrifuge tube is conducted through an outlet conduit of the air-flow fitting.

37. The method of claim 34, wherein air flowing outwardly from microcentrifuge tube is conducted into a secondary collection vessel to further separate airborne particles from the air flow.

38. The method of claim 33, further comprising performing an analysis on the particles that are separated from the air flowing through the microcentrifuge tube.

7. The apparatus of claim 6, wherein the first passageway extends generally tangentially with respect to an inner surface of the collection vessel.

8. The apparatus of claim 1, wherein:

the collection vessel is a first collection vessel, the air-inlet conduit comprises a first air-inlet conduit, and the air-outlet conduit comprises a first air-outlet conduit; and

the retaining member is adapted to be removably coupled to a second collection vessel, the retaining member further comprising a second air-inlet conduit and a second air-outlet conduit, the first air-outlet conduit being in fluid communication with the second air-inlet conduit so that air flowing through the first air-outlet conduit flows into the second collection vessel through the second air-inlet conduit and exits the second collection vessel through the second air-outlet conduit, the second air-inlet conduit and second air-outlet conduit being configured to establish a cyclonic flow path in the second collection vessel to cause airborne particles to separate from the air flowing through the second collection vessel.

9. The apparatus of claim 8, wherein the particles deposited in the first collection vessel are generally larger than the particles deposited in the second collection vessel.

10. The apparatus of claim 8, wherein the retaining member is configured to support the first and second collection vessels in the same orientation.

11. The apparatus of claim 10, wherein the retaining member is configured to support the first and second collection vessels in a generally vertically upright orientation.

12. An apparatus for use in collecting airborne particles comprising:

a collection vessel in which airborne particles are collected for analysis, the collection vessel comprising a microcentrifuge tube having an open end that is orthogonal to a line extending longitudinally with respect to the tube;

Box No. VIII (iv) DECLARATION: INVENTORSHIP (only for the purposes of the designation of the United States of America)

The declaration must conform to the following standardized wording provided for in Section 214; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box VIII (iv). If this Box is not used, this sheet should not be included in the request.

**Declaration of Inventorship (Rules 4.17(iv) and 51*bis*.1(a)(iv))
for the purposes of the designation of the United States of America**

I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought.

This declaration is directed to the international application of which it forms a part (if filing declaration with application).

This declaration is directed to international application No. PCT/US2004/032378 (if furnishing declaration pursuant to Rule 26*ter*).

I hereby declare that my residence, mailing address, and citizenship are as stated next to my name.

I hereby state that I have reviewed and understand the contents of the above-identified international application, including the claims of said application. I have identified in the request of said application, in compliance with PCT Rule 4.10, any claim to foreign priority, and I have identified below, under the heading "Prior Applications," by application number, country or Member of the World Trade Organization, day, month and year of filing, any application for a patent or inventor's certificate filed in a country other than the United States of America, including any PCT international applications designating at least one country other than the United States of America, having a filing date before that of the application on which foreign priority is claimed.

Prior Applications:

I hereby acknowledge the duty to disclose information that is known by me to be material to patentability as defined by 37 C.F.R. § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the PCT international filing date of the continuation-in-part application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Inventor's Signature: Teh-Hsun B. Chen
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Date: 02/16/2005
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26*ter* after the filing of the international application)

Name: FEATHER, Gregory

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Date: 02/16/05
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26*ter* after the filing of the international application)

☒ This declaration is continued on the following sheet, "Continuation of Box No. VIII (iv)".

Sheet No. 2

Continuation of Box No. VIII (i) to (v) DECLARATION

If the space is insufficient in any of Boxes No. VIII (i) to (v) to furnish all the information, including in the case where more than two inventors are to be named in Box No VIII (iv), in such case, write "Continuation of Box No. VIII " (indicate the item number of the box) and furnish the information in the same manner as required for the purposes of the box in which the space was insufficient. If additional space is needed in respect of two or more declarations, a separate continuation box must be used for each such declaration. If this Box is not used, this sheet should not be included in the request.

Continuation of Box No. VIII (iv) DECLARATION: INVENTORSHIP

Name: KESWANI, Jyoti

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Name: EDGELL III, Herbert David

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Inventor's Signature: ..... Date: 2-16-05
(if not contained in the request, or if declaration is corrected or added under Rule 26*ter* after the filing of the international application. The signature must be that of the inventor, not that of the agent) (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26*ter* after the filing of the international application)

Name:

Residence:
(city and either US state, if applicable, or country)

Mailing Address:

Citizenship:

Inventor's Signature: .....
(if not contained in the request, or if declaration is corrected or added under Rule 26*ter* after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: .....
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26*ter* after the filing of the international application)

Name:

Residence:
(city and either US state, if applicable, or country)

Mailing Address:

Citizenship:

Inventor's Signature: .....
(if not contained in the request, or if declaration is corrected or added under Rule 26*ter* after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: .....
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26*ter* after the filing of the international application)

☐ This declaration is continued on the following sheet. "Continuation of Box No. VIII (iv)".